Section 1 E: Summary of Safety and Effectiveness for COULTER® HmX Hematology Analyzer with IRF and MRV Parameters

1.0 General Information

Device Generic Name(s):	Automated differential cell counter
Device Trade Name(s):	COULTER® HmX Hematology Analyzer COULTER® HmX Hematology Analyzer with Autoloader
Device Classification:	The COULTER® HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader are Class II medical devices. The IRF parameter is Class III.
Applicant Name and Address:	Beckman Coulter, Inc. Cellular Analysis Division 11800 SW 147 Avenue Miami, FL 33196-2500
Date:	March 13, 2001

2.0 Legally Marketed Device(s)

The modified COULTER® HmX Hematology Analyzer and COULTER® HmX Hematology Analyzer with Autoloader claim substantial equivalence to the COULTER®GEN•S™ System with IRF and MRV parameters currently in commercial distribution

FDA 510(k) Number(s): K993356

3.0 Device Description

The products are automated hematology analyzers capable of supplying a complete blood cell analysis and are capable of additionally performing a differential leukocyte cell count. Both also provide semi-automated reticulocyte analysis. The following reagents, with 510(k) numbers indicated where applicable, are qualified for use on the COULTER HmX Hematology Analyzer and COULTER HmX Hematology Analyzer with Autoloader:

- 5C® Cell Control (K912133), 5C® -ES Cell Control (K010066) and COULTER RETIC-C™ Cell control (K930119) hematology quality control materials used to monitor the instrument performance. COULTER® LIN-C® linearity control (K955334) verifies reportable range of the instruments CBC parameters.

- COULTER ISOTON® III, COULTER ISOTON® 3E and COULTER ISOTON® 4 diluents. Intended for use as a diluent for counting and sizing blood cells on COULTER® hematology analyzers.
- COULTER Lyse S® III diff and Lyse S® 4 lytic agents. Intended for the simultaneous quantitative determination of hemoglobin and for leukocyte counting and sizing on COULTER® Hematology Analyzers.
- COULTER CLENZ® cleaning agent to prevent protein buildup on surfaces
- COULTER Latron™ Primer and Latron Control (K885028) to monitor VCS performance
- COULTER RETIC Prep™ Reagent Kit (K932030). for preparing samples for reticulocyte analysis.
- COULTER HmX Pak, containing PAK LYSE lytic reagent and PAK PRESERVE to preserve leukocytes in near-native state to allow differentiation into subpopulations
- COULTER S-CAL® Calibrator , alternative to whole blood reference method of calibration. Intended for use in ensuring accurate instrument measurements.

4.0 Principle of Method:

The COULTER HmX Hematology Analyzer and HmX Hematology Analyzer with Autoloader have the same technological characteristics and are substantially equivalent to the COULTER GEN•S System analyzer with IRF and MRV. These devices utilize the Coulter Principle for enumerating and sizing blood cells, in combination with an automatic diluting and mixing devices for sample processing and a single beam photometer for hemoglobinometry. They use COULTER VCS (volume, conductivity, light scatter) technology for WBC Differential analysis and classification and reticulocyte analysis. The analyzers all use a reagent system that consists of an isotonic diluent, lytic reagents to lyse the red cells without significantly affecting the white cells and an instrument cleaner is used on both. Additionally, all systems include reagents used for reticulocyte staining and analysis.

5.0 Indications for Use:

COULTER HmX and HmX with Autoloader analyzers are quantitative, automated hematology analyzers and leukocyte differential counters For In Vitro Diagnostic Use in clinical laboratories. The COULTER® HmX Hematology Analyzers also provide semi-automated reticulocyte analysis.

6.0 Description of the modification:

The currently marketed COULTER HmX and HmX with Autoloader analyzers were modified to report Immature Reticulocyte Fraction (IRF) and Mean Reticulocyte Volume (MRV) parameters as "For In Vitro Diagnostic Use".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 3 2001

Stan Sugrue, Ph.D.
Senior Regulatory Affairs Specialist
Premarket Product Regulatory Compliance
Beckman Coulter Inc.
11800 SW 147 Avenue
MC 31-B06
Miami, Florida 33196-2500

Re: K010765
Trade Name: COULTER® HmX Hematology Analyzers with IRF and MRV Parameters
Regulation Number: 21 CFR 864.5220
Regulatory Class: III
Product Code: GKZ
Dated: March 13, 2001
Received: March 14, 2001

Dear Dr. Sugrue:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 1C: INDICATIONS FOR USE

510(k) Number (if known): ~~Not assigned~~ K010765

Device: COULTER® HmX Hematology Analyzers with IRF and MRV parameters

Indications For Use:

The COULTER® HmX Hematology Analyzer and COULTER HmX Hematology Analyzer with Autoloader with IRF and MRV parameters are quantitative, automated hematology analyzers and leukocyte differential counters For In Vitro Diagnostic Use in clinical laboratories. The COULTER® HmX Hematology Analyzer and COULTER HmX Hematology Analyzer with Autoloader also provide semi-automated Reticulocyte analysis.

21 CFR 864.5220 Automated differential cell counter

An automated differential cell counter is a device used to identify and classify one or more of the formed elements of blood.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

Prescription Use ✓
OR
Over-The-Counter Use
(Per 21 CFR 801.109)